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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Donor Suitability Workshop: Donor History of Hepatitis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Blood Donor Suitability Workshop: Donor History of Hepatitis.'' The purpose of the workshop is to discuss whether prospective blood donors with a history of viral hepatitis should be deferred from donating blood.

Date and Time: The workshop will be held on Wednesday, July 21, 1999, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at Natcher Auditorium, Bldg. 45, 45 Center Dr., National Institutes of Health, 8800 Rockville Pike, Bethesda, MD.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration: Early registration is recommended. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number), to the contact person on or before Friday, July 2, 1999.

Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance.

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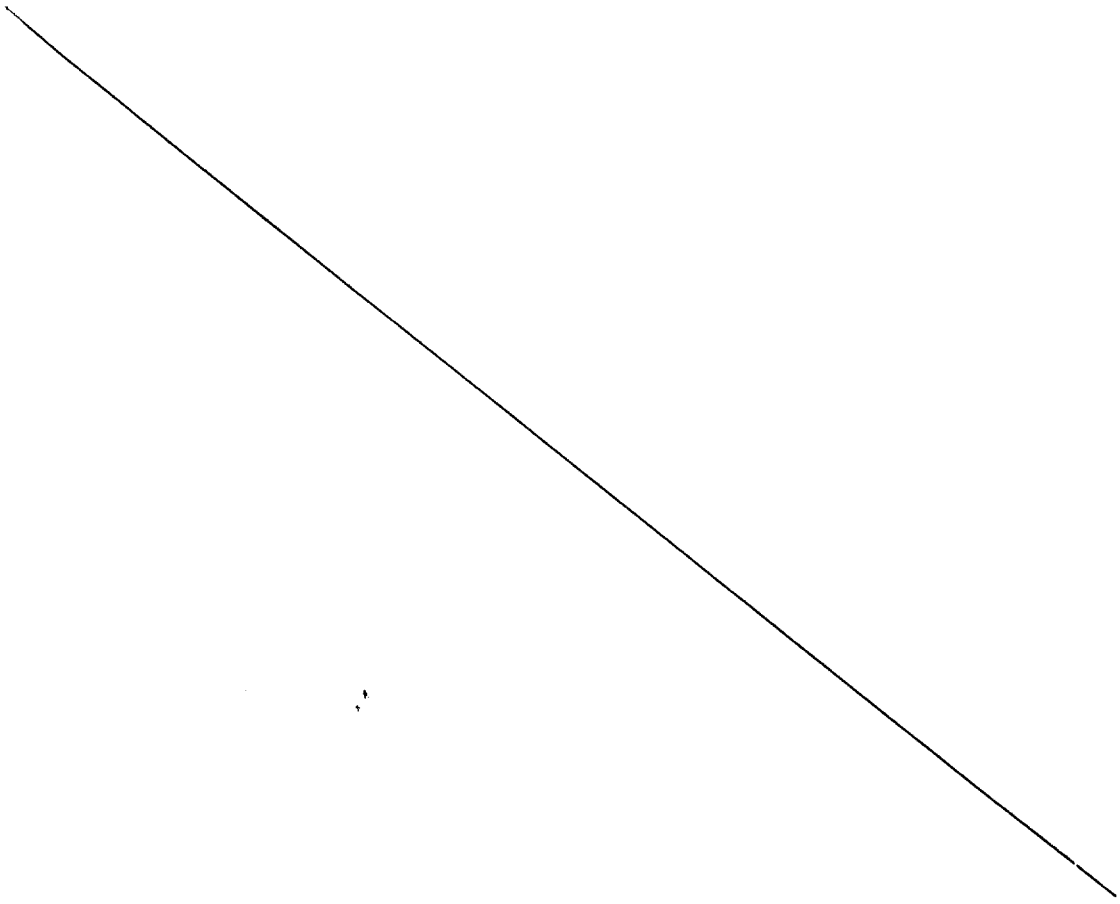
Agenda: The public workshop is intended to discuss a variety of issues concerning blood donor deferrals based on a history of viral hepatitis. These issues include, but are not limited to, the following: (1) Definitions and clarification of terms such as ''history of hepatitis'' and ''history of jaundice'' in the context of blood donation; (2) whether a prospective blood donor with a history of hepatitis A, who is anti-HAV IgG positive, is an unacceptable donor; (3) whether deferrals are appropriate for individuals with a history of viral hepatitis that was documented to be due to some other virus other than hepatitis A through G; and (4) whether a history of hepatitis in the absence of positive viral marker tests for hepatitis preclude blood donations.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the workshop at a cost of 10 cents per page.



The workshop transcript will also be available on the Center for Biologics Evaluation and Research website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: 6/18/99
June 18, 1999

William Hubbard

William K. Hubbard
Acting Deputy Commissioner for
Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Jan Windsor

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F